

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65**

**NOTICE OF PROPOSED RULEMAKING
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**AMENDMENT TO SECTION 25805
SPECIFIC REGULATORY LEVELS:
CHEMICALS CAUSING REPRODUCTIVE TOXICITY**

BISPHENOL A

JANUARY 25, 2013

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to adopt a Proposition 65¹ Maximum Allowable Dose Level (MADL) of 290 micrograms per day for exposures to bisphenol A (BPA) by amending Section 25805(b) of Title 27 of the California Code of Regulations.²

BPA is currently being considered for listing via the authoritative bodies listing mechanism as known to cause reproductive toxicity. In the event that BPA is not listed, OEHHA will not proceed with the adoption of this MADL. OEHHA is proposing this MADL at this time to assist the public in assessing the potential impact of the listing.

PUBLIC PROCEEDINGS

Any written comments concerning this proposed action, regardless of the form or method of transmission, must be received by OEHHA by 5:00 p.m. on **March 11, 2013**, the designated close of the written comment period. All comments received will be posted on the OEHHA website at the close of the public comment period.

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et seq.*, referred to herein as "Proposition 65" or "The Act."

² All further references are to sections of Title 27, Cal. Code of Regs., unless otherwise indicated.

The public is encouraged to submit written information via e-mail, rather than in paper form. Send e-mail comments to P65Public.Comments@oehha.ca.gov. Please include "BPA MADL" in the subject line. Hard-copy comments may be mailed, faxed, or delivered in person to the appropriate address below.

Mailing Address: Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-23B
Sacramento, California 95812-4010
Fax: (916) 323-2610
Street Address: 1001 I Street
Sacramento, California 95814

A public hearing on this proposed regulatory amendment will be scheduled on request. To request a hearing, please send an e-mail to Monet Vela at monet.vela@oehha.ca.gov or to the address listed above by no later than **February 25, 2013**. OEHHA will mail a notice of the hearing to the requester and interested parties on the Proposition 65 mailing list for regulatory public hearings. The notice will also be posted on the OEHHA web site at least ten days before the public hearing date. The notice will provide the date, time and location of the hearing.

If a hearing is scheduled and you have special accommodation or language needs, please contact Monet Vela at (916) 323-2517 or monet.vela@oehha.ca.gov at least one week in advance of the hearing. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

CONTACT

Please direct inquiries concerning the proposed regulatory action described in this notice to Monet Vela, in writing at the address given above, via e-mail to monet.vela@oehha.ca.gov or by calling (916) 323-2517. Susan Luong is a back-up contact person for inquiries concerning processing of this action and is available at susan.luong@oehha.ca.gov or by telephone at (916) 327-3015

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Proposition 65 prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity, without first giving clear and reasonable

warning to such individual³. The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into any source of drinking water⁴. Warnings are not required and the discharge prohibition does not apply when exposures are insignificant.⁵ The MADL provides guidance for determining when an exposure is insignificant.⁶

Details on the basis for the proposed MADL for BPA are provided in the initial statement of reasons for this regulatory amendment, which is available on request from Monet Vela and is posted on the OEHHA web site at www.oehha.ca.gov.

The proposed MADL was derived using scientific methods outlined in Section 25803.

The proposed regulation would adopt the following MADL for BPA, by amending Section 25805 as follows (addition in underline):

(b) Chemical Name	Level (Micrograms/day)
...	
<u>Bisphenol A</u>	<u>290</u>
...	

No Inconsistency or Incompatibility with Existing Regulations

OEHHA has determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations because it does not impose any mandatory requirements on businesses, state or local agencies and does not address compliance with any other law or regulation.

Benefits of the Proposed Regulation

Some businesses may not be able to afford the expense of establishing a MADL and therefore may have to defend litigation for a failure to warn or for a prohibited discharge of the listed chemical. Adopting this regulation will save these businesses those expenses and may reduce litigation costs. By providing a MADL, this regulatory proposal does not require but may encourage businesses to lower the amount of the

³ Health and Safety Code section 25249.6

⁴ Health and Safety Code section 25249.5

⁵ Health and Safety Code sections 25249.9 and 25249.10

⁶ See Sections 25801 through 25805

listed chemical in their products to a level that does not cause a significant exposure. This in turn may reduce exposures to chemicals that cause reproductive harm.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS

Impact on the Creation, Elimination, or Expansion of Jobs/Businesses in California:

This regulatory proposal will not affect the creation or elimination of jobs within the State of California. Proposition 65 requires businesses with ten or more employees to provide warnings when they expose people to chemicals that are listed under Proposition 65 as known to cause cancer or developmental or reproductive harm. The law also prohibits the discharge of listed chemicals into sources of drinking water. If BPA is eventually listed under Proposition 65, businesses who manufacture, distribute or sell products with BPA in the state would have to provide a warning if their product or activity exposes the public or employees to this chemical.

This regulatory proposal will have no effect on the creation/elimination/expansion of California businesses.

Benefits:

By providing an MADL, this regulatory proposal spares businesses the expense of calculating their own MADL and may also enable them to reduce or avoid litigation costs. In addition, the MADL does not require, but may encourage, businesses to lower the amount of the listed chemical in their product to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians.

AUTHORITY

Health and Safety Code Section 25249.12.

REFERENCE

Health and Safety Code Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

Because Proposition 65 expressly⁷ does not apply to local agencies or school districts, OEHHA has determined the proposed regulatory action would not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

COSTS OR SAVINGS TO STATE AGENCIES

Because Proposition 65 expressly⁸ does not apply to any State agency, OEHHA has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

EFFECT ON FEDERAL FUNDING TO THE STATE

Because Proposition 65 expressly⁹ does not apply to any federal agency, OEHHA has determined that no costs or savings in federal funding to the State will result from the proposed regulatory action.

EFFECT ON HOUSING COSTS

OEHHA has determined that the proposed regulatory action will have no effect on housing costs because it provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

Because the proposed MADL provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses, OEHHA has made an initial determination that the adoption of the regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

⁷ See Health and Safety Code section 25249.11(b)

⁸ See Health and Safety Code section 25249.11(b)

⁹ See Health and Safety Code section 25249.11(b)

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The proposed MADL was developed to provide compliance assistance for businesses in determining whether a warning is required or a discharge is prohibited. The MADL provides a level of exposure at or below which a warning is not required and a discharge is not prohibited. Use of the MADL is not mandatory. The implementing regulations allow a business to calculate its own level.¹⁰ However, conducting such an analysis can be expensive and time consuming, and the resulting levels may not be defensible in an enforcement action.

EFFECT ON SMALL BUSINESSES

OEHHA has determined that the proposed regulation will not impose any mandatory requirements on small business. Rather, the proposed regulation will provide compliance assistance for small businesses subject to the Act because it will help them determine whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition of the Act.

CONSIDERATION OF ALTERNATIVES

The OEHHA must determine that no reasonable alternative considered by the OEHHA or that has otherwise been identified and brought to the attention of the OEHHA would either be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

OEHHA has prepared and has available for public review an Initial Statement of Reasons for the regulation, all the information upon which the regulation is based, and the text of the regulation. A copy of the Initial Statement of Reasons, the text of the regulation and documents used by OEHHA to develop the proposed regulation are available upon request from OEHHA at the address and telephone number indicated above. These documents are also posted on OEHHA's Web site at www.oehha.ca.gov.

¹⁰ Section 25801 *et seq.*

AVAILABILITY OF CHANGED OR MODIFIED TEXT

The full text of any regulation which is changed or modified from the express terms of this proposed action will be made available at least 15 days prior to the date on which OEHHA adopts the resulting regulation. Notice of the comment period on changed regulations and the full text will be mailed to individuals who testified or submitted written comments at the public hearing, if held, or whose comments were received by OEHHA during the prior public comment period, and anyone who requests notification from OEHHA of the availability of such changes. Copies of the notice and the changed regulation will also be available on the OEHHA Web site at www.oehha.ca.gov.

FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons for this regulatory action may be obtained, when it becomes available, from OEHHA at the address and telephone number indicated above, and on the OEHHA website at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

Allan Hirsch
Chief Deputy Director

Dated: January 25, 2013